The Patent Office

09/381561

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I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears an amendment, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

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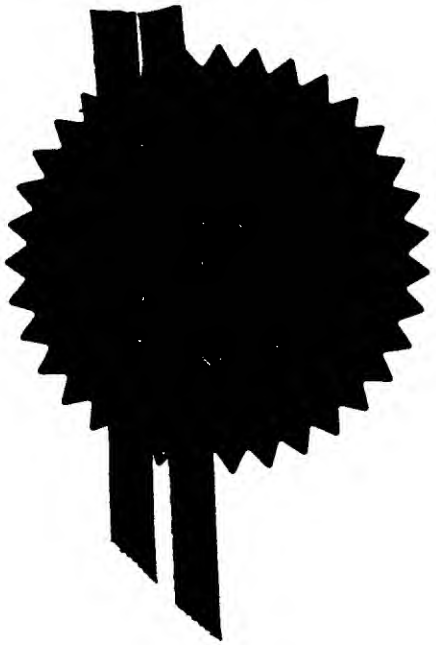

PRIORITY DOCUMENT

Signed Andrew Gregg

Dated 29th May 1998

For official use

THE PATENT OFFICE
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19 MAR 1997
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19MAR97 E261674-1 C21131
P01/7700 25.00

Your reference JJ PAPP1

C21131

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Notes
Please type, or write in dark ink using CAPITAL letters. A prescribed fee is payable for a request for grant of a patent. For details, please contact the Patent Office (telephone 071-438 4700).

Rule 16 of the Patents Rules 1990 is the main rule governing the completion and filing of this form.

❷ Do not give trading styles, for example, 'Trading as XYZ company', nationality or former names, for example, 'formerly (known as) ABC Ltd' as these are not required.

Warning
After an application for a Patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977 and will inform the applicant if such prohibition or restriction is necessary. Applicants resident in the United Kingdom are also reminded that under Section 23, applications may not be filed abroad without written permission unless an application has been filed not less than 6 weeks previously in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction revoked.

The Patent Office

Request for grant of a Patent

Form 1/77

Patents Act 1977

❶ Title of invention

1 Please give the title of the invention: DIAGNOSTIC AND ANALYTICAL DEVICES

❷ Applicant's details

☑ ~~First or~~ **only applicant**

2a If you are applying as a corporate body please give:

Corporate name

Country *(and State of incorporation, if appropriate)*

2b If you are applying as an individual or one of a partnership please give in full:

Surname JACKSON

Forenames JAMES RICHARD

2c **In all cases**, please give the following details:

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WOODS LANE
CLIDDESDEN
HAMPSHIRE

UK postcode *(if applicable)* RG25 2JF

Country UK

ADP number *(if known)* 07178023001

❼ *The answer must be 'No' if:*
- *any applicant is not an inventor*
- *there is an inventor who is not an applicant, or*
- *any applicant is a corporate body.*

❼ Inventorship

7 Are you (the applicant or applicants) the sole inventor or the joint inventors?

Please mark correct box

Yes [✓] No [ ] ➡ ***A Statement of Inventorship on Patents Form 7/77 will need to be filed (see Rule 15).***

❽ *Please supply duplicates of claim(s), abstract, description and drawing(s).*

❽ Checklist

8a Please fill in the number of sheets for each of the following types of document contained in this application.

52

Continuation sheets for this Patents Form 1/77	C		
Claim(s)		Description	3
Abstract		Drawing(s)	2

8b Which of the following documents also accompanies the application?

Please mark correct box(es)

Priority documents *(please state how many)*	
Translation(s) of Priority documents *(please state how many)*	
Patents Form 7/77 – Statement of Inventorship and Right to Grant *(please state how many)*	
Patents Form 9/77 – Preliminary Examination/Search	
Patents Form 10/77 – Request for Substantive Examination	

❾ *You or your appointed agent (see Rule 90 of the Patents Rules 1990) must sign this request*

❾ Request

I/We request the grant of a patent on the basis of this application.

Please sign here ➡ Signed James Jackson Date 18 (day) 03 (month) 97 (year)

A completed fee sheet should preferably accompany the fee

Please return the completed form, attachments and duplicates where requested, together with the prescribed fee to either:

☑ ***The Comptroller***
The Patent Office
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25 Southampton Buildings
London
WC2A 1AY

RECORDING ASSAY DEVICE OVERVIEW

Description of concept

The device is intended for use as a diagnostic assay device or other analytical test device.

The assay procedure is run within the device immediately following addition of sample.

The sample may be diluted by a buffer in certain circumstances. Alternatively, there may be a separate addition of buffer to the device in conjunction with the sample.

The assay responses are recorded by the device internally in a stable manner and are not available for viewing by the operator without further processing.

The result of the assay is determined by a separate procedure in which the recorded assay responses are retrieved and analysed in order to assign a value or classification to the sample. This procedure is performed at a different site from that where the assay was originally run, such as a central laboratory. The portion of the device which contains the recorded result may be detached and mailed to this site.

The device contains controls or calibrators to allow a qualitative or quantitative result to be determined.

The basic assay running format may be any existing or future technique. Current candidate techniques include lateral flow, flow through and capillary action. Lateral flow is the most immediately applicable format.

The novelty of the device

The prime novel feature of the device is the recording by the device of the assay responses given by sample/s and calibrators or controls, at the point of running of the assay, for subsequent further analysis leading to quantification or classification of the sample.

The assay may thus be run at the point of extraction of sample without the result being known until subsequent processing, which may be performed elsewhere.

The result of the assay may therefore remain unknown to the person using the device, if this person is excluded from the subsequent processing.

The detached recording unit is free from contamination of sample and sample components, rendering it safe to handle and mail.

The use of a microprocessor or other electronic recording device is particularly novel.

Lateral-flow assay device format

The lateral flow assay device would incorporate channels in which the sample and calibrators or controls were assayed separately. The device would contain assay reagents.

Each discrete channel would be fed by a single fluid reservoir or alternatively two or more reservoirs would be used; one for the sample and additional reservoirs for the calibrators or controls.

The reservoirs would be wetted with sample; an additional buffer/s may be used if required by the procedure. Such buffers may contain assay reagents.

Lateral-flow assay device channels

The lateral-flow assay device channels could comprise either of the following;

i Multiple channels formed in paper or other water permeable material by impregnation with polymers to form water impermeable regions.

ii Multiple channels formed in nitrocellulose or other water permeable diagnostic or filter membrane by impregnation with wax to form water impermeable regions.

iii Formation of strips of water permeable material within a sheet of the material by cutting regions from a sheet of the material, in order to form multiple channels.

iv Printing (eg by silk screen) of a water permeable material (eg nitrocellulose or other material used to make diagnostic and filter membranes) in emulsion or other fluid form onto a water impermeable surface to create channels of the water permeable material.

v Multiple water permeable channels comprised of any material and produced by any method.

vi A single water permeable channel or strip comprised of any material and produced by any method.

vii A channel of free space, within a water impermeable structure, forming a capillary in which liquid may flow by capillary action. This technique is sometimes referred to as a "capillary flow" diagnostic device.

viii Other types of channel.

See Figure 1.

Assay detection systems for recording of responses

Several assay detection systems are readily applicable to the device;

i Recording of an electrochemical reaction by a microprocessor or other solid-state device. Amperometric and potentiometric assay detection techniques are appropriate. This is the preferred detection system, as the removable recording system can be kept from contacting physically with any of the components of the sample, thus rendering it completely safe from infectious risk on handling. See Figure 2.

ii Recording of a photometric reaction by a photographic or other light sensitive film or device. Chemiluminescence and fluorescence are appropriate.

iii Reflectance or transmittance photometry; production of a stable dye on a surface by biochemical or chemical reaction, including ELISA.

iv Microparticles, including polymers, metallic and non-metallic elements and other materials.

v Soluble coloured substances, including dyes. These would be determined by a light reflectance technique (including fluorimetry) or a light transmittance technique or another technique related to any specific feature of any soluble substance used.

vi Other assay detection systems.

Intended application of the device

The device is used for performing diagnostic or other analytical test procedures. Where diagnostic tests are performed, candidate applications include;

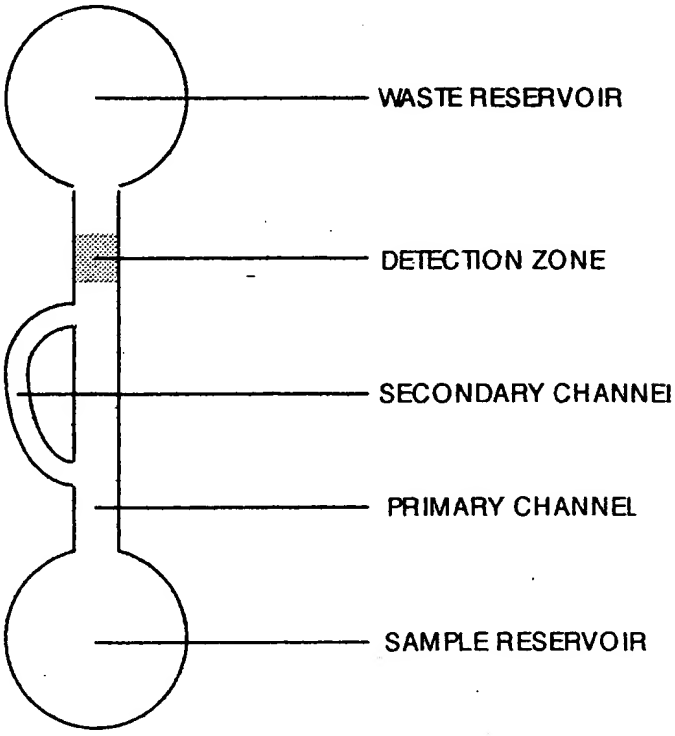
i Home (OTC) diagnostics; in particular for HIV and other clinical conditions in which it is undesirable for the patient to have direct access to the result.

ii Decentralised testing situations in which a rapid result is not required but it is desirable to test a fresh sample at the point of collection, such as patient monitoring at home or in managed care facilities.

iii Clinical trials for drugs and other treatments, in which a rapid result is not required but it is desirable to test a fresh sample at the point of collection.

Figure One Example channel format in recording assay device

EXAMPLE - CONFIGURATION OF ASSAY CHANNE

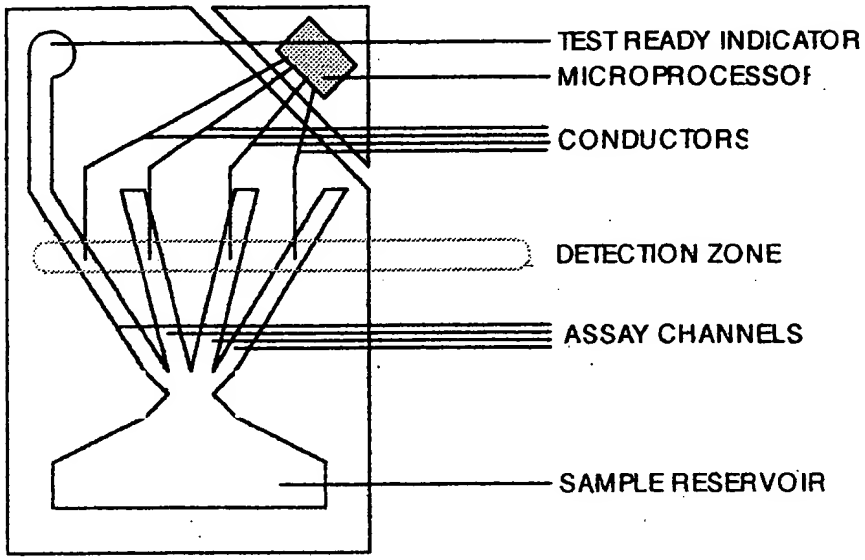


PRIMARY CHANNEL	Contains primary assay reagents
SECONDARY CHANNEL	Contains secondary assay reagents
DETECTION ZONE	Contains detection system reagents

NOTE: THERE MAY BE ADDITIONAL SECONDARY CHANNELS AND OTHER VARIATIOI

Figure Two Recording assay device with microprocessor

EXAMPLE - INTERNAL LAYOUT



EXAMPLE - EXTERNAL VIEW